K022981

SEP 12 2002

510(k) SUMMARY
For the Inion CPS™ 2.5/2.8 Screw
September/6/2002

ADMINISTRATIVE INFORMATION

Manufacturer´s Name: Inion Ltd.
Lääkärinkatu 2
FIN-33520 Tampere

Contact Person:
Hanna Marttila
Regulatory Affairs Manager
Lääkärinkatu 2
FIN-33520 Tampere
Phone: +358 3 230 6600
Fax: +358 3 230 6601

DEVICE NAME

Classification Name: Screw, Fixation, Bone
Common/Usual Name: bone fixation fastener
Trade Name: Inion CPS™ 2.5/2.8 Screw

ESTABLISHMENT REGISTRATION NUMBER

9710629

DEVICE CLASSIFICATION AND PRODUCT CODE

As shown in 21 CFR 888.3040 screws are classified as Class II. Screws have been assigned Product Code HWC.

PREDICATE DEVICE

(1) Inion CPS™ 1.5/2.0/2.5 Bioabsorbable Fixation System (K010352)

INTENDED USE

The Inion CPS™ 2.5/2.8 Screws are intended for use in trauma and reconstructive procedures in the craniofacial skeleton, midface, maxilla and mandible (in conjunction with appropriate maxillomandibular fixation) as a part of the Inion CPS™ 1.5/2.0/2.5 Bioabsorbable Fixation System.

a) Fractures of the cranium, midface, maxilla and mandible.
b) Infant craniofacial surgery (i.e. craniosynostosis, congenital malformations).
c) LeFort (I, II, III) osteotomies.
d) Pediatric reconstructive procedures.
e) Orthognathic or reconstructive procedures of the cranium, midface, maxilla or mandible.
f) Craniotomy flap fixation.

The Inion CPS™ Screws are not intended for use in and is contraindicated for: Mandibular tumor resection; Active or potential infection; Patient conditions including limited blood supply, insufficient quantity or quality of bone; and where patient cooperation cannot be guaranteed (e.g., alcoholism, drug abuse). The system is not intended for use in the mandible without appropriate maxillomandibular fixation.

DEVICE DESCRIPTION

The Inion CPS™ 2.5/2.8 Screw is provided with diameters of 2.5 mm and 2.8 mm. Length of the screw is 6 to 23 mm. The Inion CPS™ 2.5/2.8 Screws are made of PLDLA/TMC, same basic material as with predicate device.

EQUIVALENCE TO MARKETED PRODUCTS

The Inion CPS™ 2.5/2.8 Screws are a modification to currently marketed Inion CPS™ 1.5/2.0/2.5 Bioabsorbable Fixation System. Inion CPS™ 2.5/2.8 Screws have the same technological characteristics and it is offered with the same packaging and sterility options as with the Inion CPS™ System identified above. New feature is a minor change in material composition specifically in copolymer ratio. The Inion CPS™ 2.5/2.8 Screws have the same intended use and principles of operation as Inion CPS™ 1.5/2.0/2.5 Bioabsorbable Fixation System and there is no change in safety or efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 12 2002

Ms. Hanna Marttila
Regulatory Affairs Manager
Inion Limited
Laakarinkatu 2
FN-33520 Tampere
FINLAND

Re: K022981
Trade/Device Name: Inion CPS™ 2.5/2.8 Screw
Regulation Number: 872.4760 and 888.3040
Regulation Name: Bone Plate and Smooth or Threaded Metallic Bone Fixation Fastener
Regulatory Class: II
Product Code: JEY and HWC
Dated: September 6, 2002
Received: September 9, 2002

Dear Ms. Marttila:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618 . Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Patricia Cicirelli /for

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K022981

D STATEMENT OF INDICATIONS FOR USE

Applicant: Inion Ltd.
510(k) Number:
Device Name: Inion CPS ™ 2.5/2.8 Screw

Indications For Use:

Indications:

A. General indications: The Inion CPS™ 2.5/2.8 Screws are intended for use in trauma and reconstructive procedures in the craniofacial skeleton, midface, maxilla and mandible (in conjunction with appropriate maxillomandibular fixation) as a part of the Inion CPS™ 1.5/2.0/2.5 Bioabsorbable Fixation System.

B. Specific indications:
   - Fractures of the cranium, midface, maxilla and mandible.
   - Infant craniofacial surgery (i.e. craniosynostosis, congenital malformations).
   - LeFort (I, II, III) osteotomies.
   - Pediatric reconstructive procedures.
   - Orthognathic or reconstructive procedures of the cranium, midface, maxilla or mandible.
   - Craniotomy flap fixation.

Contraindications:

The Inion CPS™ Screws are not intended for use in and is contraindicated for:

1. Mandibular tumor resection
2. Active or potential infection
3. Patient conditions including limited blood supply, insufficient quantity or quality of bone; and where patient cooperation cannot be guaranteed (e.g., alcoholism, drug abuse)
4. DO NOT USE in the mandible without appropriate maxillomandibular fixation.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K022981